

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

)	
UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
SAMUEL ADAM COX, III)	Civil Action No. 08-cv-2832-BBD-tmp
)	
Plaintiff-Relator,)	
)	
)	JURY TRIAL DEMAND
v.)	
)	
SMITH & NEPHEW INC.,)	
)	
Defendant.)	
)	

AMENDED COMPLAINT

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false or fraudulent claims and statements made, used or caused to be made or used by the Defendant to the United States in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended (hereinafter “FCA”).

2. The False Claims Act (hereinafter the “FCA”), originally enacted in 1863 during the Civil War, was substantially amended by the False Claims Amendments Act of 1986, signed into law on October 17, 1986.

3. Congress enacted the 1986 amendments to enhance the Government's ability to recover losses sustained as a result of fraud against the United States and to provide a private cause of action for the protection of employees who act in furtherance of the purposes of the Act. Congress amended the FCA after finding that fraud in federal programs and procurement is

pervasive and that the FCA, which Congress characterized as the primary tool for combating fraud in government contracting, was in need of modernization.

4. In its current form, the FCA provides that any person who knowingly submits a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government, including attorneys' fees. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring a private cause of action for himself or herself and on behalf of the Government, and to share in any recovery resulting from that action. The complaint is to be filed under seal for 60 days (without service on the Defendant during such 60-day period) to enable the Government (a) to conduct its own investigation without the Defendant's knowledge and (b) to determine whether to join the action.

5. The FCA was further amended by the Fraud Enforcement Recovery Act ("FERA") passed by Congress and signed into law on May 20, 2009 for the express purpose of strengthening the tools available to combat fraud and to overturn judicial decisions that had weakened the False Claims Act. Pub. L. No. 111-21, 123 Stat. 1617 (2009).

6. While most of the new provisions apply only to claims after the effective date of the statute, Congress determined that 31 USC § 3729(a)(1)(B), which revised the former section designated as 31 USC § 3729(a)(2) pertaining to liability for false statements, "...shall take effect as if enacted on June 7, 2008, and shall apply to all claims . . . that are pending on or after that date." 4(f) of FERA, 123 Stat. at 1625 (see note following 31 USC § 3729).

7. For claims prior to June 7, 2008, 31 USC § 3729(a)(2) holds liable any person who "knowingly makes, uses, or causes to be made or used, a false record or statement *to get a false or fraudulent claim paid or approved* by the Government." *Id.* (emphasis added)

8. For claims after June 7, 2008, 31 USC § 3729(a)(1)(B) holds liable any person who “knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false or fraudulent claim.” *Id.* (emphasis added)

9. Based on these provisions, Plaintiff-Relator seeks to recover damages and civil penalties arising from Defendant having knowingly made, used or caused to be made or used false records or statements to the Government certifying that Defendant’s products were manufactured in the United States, when in fact those products were manufactured in non-designated countries in violation of the Trade Agreements Act (hereinafter “TAA”), 19 U.S.C. 2501, *et seq.*

10. Plaintiff-Relator also seeks to recover damages and civil penalties arising from Defendant’s presentation, on the basis of Defendant’s aforementioned false certifications of TAA compliance, of false claims for payment and reimbursement by the United States Government in connection with the selling of non-compliant products to the United States Government.

11. Plaintiff-Relator has direct and independent knowledge that Defendant has violated the False Claims Act by offering for sale and selling products to the United States Government that did not originate in designated countries under the TAA, while at the same time knowingly making false records or statements to the Government certifying that Defendant’s products were manufactured in the United States.

PARTIES

12. Plaintiff-Relator Samuel Adam Cox III (“Plaintiff-Relator,” “Plaintiff-Relator Cox” or “Mr. Cox”) is a resident of Memphis, Tennessee and was formerly employed by Smith & Nephew, Inc. in its Tennessee office as the Information Technology Global Director of Enterprise Resource Planning. In this capacity, Mr. Cox gained direct and independent

knowledge of the allegations contained in this Complaint.

13. Plaintiff-Relator Cox was employed by Defendant in the above-described capacity from mid-December 2007 to September 2008, when Smith & Nephew terminated him in retaliation for his repeated attempts to bring Smith & Nephew's illegal activities to the attention of his superiors.

14. Defendant Smith & Nephew, Inc. ("Defendant," "Smith & Nephew" or "the Company") is a British medical devices company headquartered in London and active internationally in the sale of medical devices to government and non-government customers. Smith & Nephew is a constituent of the Financial Times Stock Exchange 100 Index, a share index of the 100 most capitalized companies on the London Stock Exchange. According to Smith & Nephew's website, Smith & Nephew operates in 32 countries and generates annual sales of \$3.4 billion. Over the last five years, the Company's revenue has increased from \$1.9 billion to over \$3.4 billion in 2007. The company employs over 9,600 people.

15. Since at least 2002, Defendant has sold medical devices to the United States Government under the General Services Administration ("GSA") Multiple Awards Schedule and under the Federal Supply Schedule Program ("FSSP") managed by the Veterans Affairs National Acquisition Center, and in doing so has agreed to comply with the TAA's prohibition barring the sale of products originating in non-designated countries to the United States Government.

JURISDICTION AND VENUE

16. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331. It also has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732, which specifically provides for jurisdiction over actions brought under the False Claims Act, 31 U.S.C. §§ 3729 and 3730.

17. There has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint.

18. This Court has personal jurisdiction over Defendant Smith & Nephew pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because Defendant has at least minimum contacts with the United States. Moreover, Defendant is headquartered in and transacts or has transacted business in the Western District of Tennessee.

19. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Defendant can be found in and transacts or has transacted business in the Western District of Tennessee.

BACKGROUND

20. The Federal Trade Agreements Act (“TAA”) holds that in certain situations, U.S. Government procurements from companies are subject to domestic preference requirements.

21. The TAA applies to U.S. Government procurements valued in excess of specified threshold amounts (revised about every two years). Currently, the TAA applies to acquisitions of supplies or services valued in excess of about \$194,000, but the thresholds vary by type of acquisition, the government agency that is purchasing the product, and the product’s country of origin.

22. Under the TAA, if the value of the U.S. government’s purchase is in excess of the applicable threshold, the U.S Government may only acquire end products that are either made in the United States or listed as “Eligible Products” from a “Designated Country” under applicable law.

23. The categories of “designated countries” are: (1) WTO member and GPA signatory, (2) NAFTA country, (3) Caribbean Basin Country, (4) Least Developed Country, and, (5) for Department of Defense purchases, one of the 21 countries with which the U.S. has a

“Memorandum of Understanding” (“MOU”).

24. According to the TAA, if the value of the U.S. Government’s purchase is in excess of the applicable threshold, the U.S Government can only acquire products that meet the “End Product” test.

25. According to the End Product test, to be eligible for purchase by the Government, an end product must either be: (a) mined, produced, or manufactured in the U.S. or a “Designated Country”; or (b) “Substantially Transformed” in the U.S. or a “Designated Country.” “Substantial Transformation” means that the product is made into a “new and different article of commerce” with a name, character, or use distinct from that of the article or articles from which it was transformed. An article is not substantially transformed by minor manufacturing or combining processes that leave the identity of the article intact. The assembly process must be complex and meaningful.

**SMITH & NEPHEW’S FALSE CLAIMS AND STATEMENTS
REGARDING TRADE ACT AGREEMENT COMPLIANCE**

26. Smith & Nephew is intentionally and knowingly selling non-compliant products to the United States government in violation of the Trade Agreements Act.

27. The Department of Veterans Affairs Federal Supply Schedules Medical Equipment and Supplies Team is responsible for negotiating, awarding, administering and maintaining contracts for medical equipment and supplies, including but not limited to: bandages, scopes, colostomy/ostomy products, wound drainage systems and kits, hospital clothing, vision screening and test equipment, anesthesia equipment, physiological monitors, defibrillators, hand surgical instruments, implants, medication and supply packaging and dispensing equipment.

28. In early 2003, the Department of Veterans Affairs announced the award of a

contract (Number V797P-4403a) to Smith & Nephew, Inc. to provide Medical Supplies and Services to the United States Government pursuant to Schedule 65 IIA. *See* Exhibit 2 at 6.

29. Smith & Nephew's current contract (Number V797P-4403a) expires on November 30, 2012. *See* Exhibit 1-B.

30. As of January 20, 2010, Smith & Nephew, Inc. had 7975 products listed for sale to the United States Government through the Contract Catalog Search Tool's ("CCST") MedSurg Non-Pharmaceutical Catalog under Contract No. V797P-4403a. *See* Exhibit 3.

31. Smith & Nephew also lists for sale and sells products to the United States Government under the General Services Administration ("GSA") Multiple Awards Schedule. As of January 20, 2010, Smith & Nephew, Inc. had 7801 products listed for sale to the United States Government through the GSA Advantage website under Contract No. V797P-4403A. *See* Exhibit 4.

32. Of the Smith & Nephew products made available for sale on the GSA website, under "Product Detail," all products are listed as "Made In: UNITED STATES OF AMERICA." *See* Exhibit 1-A.

33. While the VA-FSS catalog pages feature no explicit affirmation of country of origin for each product, the FSS explicitly requires that all products sold through the FSS Program must be in compliance with the Trade Agreements Act. *See* Exhibit 5 at 13.

34. In fact, however, at least 107 products that are listed for sale through both the GSA and VA-FSS websites are regularly purchased by Smith & Nephew from Straits Orthopaedics, a Malaysian medical device manufacturer whose principal business is the production, cleaning and packaging of orthopaedics devices and accessories (trauma and reconstructive) and wound care products. *See* Exhibit 1, Exhibit 6.

35. Malaysia is a non-designated country under the TAA. *See* Exhibit 5 at 15.

36. Since the estimated dollar value of each GSA Schedule exceeds the established Trade Agreements Act (TAA) threshold, the GSA holds that the TAA is applicable to all Schedules. In accordance with the TAA, only products made in the United States or designated country end products shall be offered and sold under Schedule contracts. Smith & Nephew's contract with the United States Government (Contract No. V797P-4403A) is therefore covered by the TAA's country of origin provisions, such that only products made in the United States or designated country end products may be offered and sold to the United States Government under that contract.

37. By the express terms of Contract No. V797P-4403A, Defendant Smith & Nephew certified that it would only sell end products under this contract to the United States Government that originate in designated countries, and that it would not sell end products to the United States Government that originate in non-designated countries like Malaysia.

38. Nevertheless, Smith & Nephew's policy and practice concerning the purchase, receipt, storage, sale and shipment of items purchased from Malaysia, and presumably from other non-designated countries, ensure that Defendant is never able to certify truthfully that a given end product sold to the United States Government originates from a permissible country of origin.

39. When Smith & Nephew purchases products from Malaysia, a purchase order is issued by Defendant to Straits Orthopaedics listing the product by its Material Number.

40. While the invoice for Straits products is issued to Smith & Nephew by the Malaysian company's Vancouver, Canada office, the products themselves are shipped directly from their manufacturer in Malaysia to one of three Smith & Nephew warehouses in Memphis,

Tennessee.

41. Once the Malaysian products have been received at one of Smith & Nephew's warehouses in Memphis, the products are cleaned, packaged, sterilized and warehoused in Memphis until they are shipped and sold to Smith & Nephew's governmental and non-governmental customers. The Malaysian products do not undergo any "substantial transformation" prior to their warehousing and/or shipment to Defendant's customers.

42. After their repackaging by Smith & Nephew in Memphis, the Malaysian products are never again visibly identified by their country of origin. Instead, their new packaging gives two addresses for Smith & Nephew: one in Memphis, Tennessee, and the other in Tübingen, Germany. Nothing on Smith & Nephew's packaging identifies the products as having originated in Malaysia.

43. It is possible to trace a Smith & Nephew product from its origin in Malaysia through its sale to the United States Government by means of the Company's computer records using the product's Material Document Number.

44. However, no effort is made by Smith & Nephew to track the country of origin of any given product once that product arrives at the Company's warehouse for repackaging and storage, nor is any effort made to segregate products originating from non-designated countries in order to ensure TAA compliance.

45. Once Malaysian products have gone through the repackaging and storage process at the Company's Memphis warehouses, the products are stored, sold and shipped without any further attention to their country of origin, despite the fact that Smith & Nephew (and only Smith & Nephew) possesses information in its databases (namely the Material Document Numbers) that would allow the Company to track the country of origin of all products sold to the United

States Government and thus to make good on its certifications of compliance with the terms of the TAA.

46. Despite the fact that Smith & Nephew's standard processing procedure for Malaysian products obscures, for all practical purposes, the country of origin of those products, Defendant nevertheless regularly certifies its compliance with the TAA and all other applicable laws.

47. In addition to the certifications of TAA compliance required by the United States Government as a standard part of its contract and procurement procedures, Smith & Nephew's internal policy requires that a product shipped to any customer must be accompanied by a Certificate of Acceptance.

48. In the Certificate of Acceptance, Smith & Nephew expressly certifies compliance with the purchasing entity's criteria for acceptance of the item or items being sold, whatever those requirements may be.

49. Defendant's TAA non-compliance is demonstrated by Exhibit 1, attached, which lists 107 end products that contemporaneous records show are purchased by Smith & Nephew from Malaysia.

50. The 107 GSA product information pages attached as Exhibit 1-A demonstrate that, as of January 2010, Smith & Nephew was offering these same 107 products for sale to the United States Government.

51. Each GSA product information page lists these same products as having been made in the United States, despite the fact that the products may have originated from Malaysia or other non-designated countries.

52. The GSA does not allow vendors to sell or list for sale on its web site any

products that originate in non-designated countries. In fact, under GSA procurement policies, vendors must specifically list all products for sale and their countries of origin before the products can be approved for sale on the website. Any product from a non-designated country cannot be listed on or sold through the GSA Advantage website.

53. Similarly, all products listed for sale through the VA-FSS program must be designated country end products, in compliance with the Trade Agreements Act. *See* Exhibit 6 at 13-15.

54. The reliance of United States Government contracting officers upon Defendant's misrepresentation that the 107 products listed in Exhibit 1-A were from designated countries led, in all likelihood, to Government procurement of items from non-designated countries, like Malaysia, in violation of the TAA.

55. Smith & Nephew has knowingly made false statements to the United States Government by virtue of its failure to correctly indicate the country of origin of the 107 products listed in Exhibit 1-A.

56. Plaintiff-Relator Cox's firsthand acquaintance with Smith & Nephew's above-described and documented violations of the False Claims Act began soon after Mr. Cox's start at the Company in December 2007.

57. Specifically, in mid-January 2008, Plaintiff-Relator Cox attended a meeting with Senior Vice President of Global Operations for Orthopaedics Bill Griffin, Global Vice President of Information Technology Jon Schaubert, and Tom Leonard, Director of Smith & Nephew's Global Distribution Center ("GDC").

58. Since the first quarter of 2007, Mr. Leonard had led the GDC in its mission to insure accurate fulfillment of customer orders in a timely manner by building a new, automated

warehouse as part of its business operations in Memphis, TN, and by implementing a Warehouse Management Software module to direct customer orders through picking, packaging and shipping.

59. During that meeting, the attendees discussed, among other issues, specific elements that were designated as beyond the scope of the GDC project. These “out of scope” elements included, *inter alia*, the country of origin selection during sales order confirmations; product registration selections (a product must be registered in a country in order to be sold in that country); and substantial transformation determination.

60. During the same meeting, Griffin and Schaubert stated that they had personal knowledge that Smith & Nephew was shipping products from its DELP Warehouse to customers in violation of country of origin laws and regulations. Nevertheless, Griffin and Schaubert determined that no changes to the scope of the GDC project would be made to address these violations.

61. Upon information and belief, Plaintiff-Relator’s supervisor Sal Chiovari, the Chief Information Officer for Smith & Nephew and a member of the Company’s Executive Staff, would not allow changes to the scope of the GDC project, even though Chiovari knew that the DELP Warehouse was making illegal shipments in violation of U.S. country of origin laws and regulations, and knew further that these violations would persist unchecked without changes in the scope of the GDC project to address the violations.

62. In late January 2008, Plaintiff-Relator Cox met with Tom Macelravery, VP of Sales/Supply Chain for Reconstructive Surgery. VP Macelravery told Plaintiff-Relator Cox that Smith & Nephew had a contract with the Department of Defense and was shipping products to the United States military—as well as to all of Defendant’s other customers—in violation of

country of origin contract requirements and regulations. VP Macelravey joked to Plaintiff-Relator that this practice was “go to jail activity.”

63. During that same week in late January 2008, Plaintiff-Relator Cox met with David Ruff, the Director of Trauma Sales/Supply Chain for Smith & Nephew. Mr. Ruff told Plaintiff-Relator that he knew Smith & Nephew was shipping items that were made in Malaysia to the United States military, and that this practice was in direct violation of country of origin requirements that were part of the Department of Defense contracts. Plaintiff-Relator Cox told Mr. Ruff that this was a very serious violation and asked if Defendant had reported the error. Mr. Ruff said that Defendant had not. Plaintiff-Relator Cox told Mr. Ruff that this was “going to jail activity.” Mr. Ruff smiled and stated that he would not look good in federal prison orange jump suits.

64. During the same conversation in January 2008, Mr. Ruff asked Plaintiff-Relator Cox whether it would be possible to expand the scope of the GDC project to address these violations. Plaintiff-Relator Cox noted that such a change would require major reconfiguration of the GDC coding, and that Mr. Chiovari had declared these issues to be beyond the scope of the project.

65. In early February 2008, Plaintiff-Relator Cox met with Mr. Schaubert in his office to discuss Smith & Nephew’s violations of the law relating to its false certifications of compliance with federal law regarding product country of origin. Mr. Cox recommended that the GDC project be corrected to remedy these violations, noting that continued violation of the law could carry severe penalties. Schaubert responded that under no terms would there be a change in the GDC project, and further threatened Plaintiff-Relator Cox that he better get on the “bus,” meaning that he better “shut-up and go-along.”

66. Also in early February 2008, Plaintiff-Relator Cox met with Steve Kahn, Vice President of Quality for Smith & Nephew. Kahn expressed his concern for the illegal activity surrounding shipments in fulfillment of Government contracts, specifically Defendant's false certifications of compliance with federal law regarding product country of origin. Kahn told Plaintiff-Relator that certain products that the United States military was purchasing from Defendant were being made in Malaysia, in direct violation of Department of Defense contract requirements. Kahn stated that he was so concerned about Smith & Nephew's illegal conduct that he had raised the issue with the Presidents of the Orthopedics Division, Mark Augusti and Joe Devivio. Kahn even started holding internal meetings with several Smith & Nephew departments, in hopes of raising internal awareness of the violations that were occurring on a daily basis at the Company. Kahn's meetings were attended by some of Smith & Nephew's Senior Management, but Kahn's concerns were never given any priority among the Company's business objectives.

67. In early February 2008, Jon Schaubert and Sal Chiovari directed Plaintiff-Relator Cox to undertake a "Country of Origin Batch Determination" project. In a meeting in early March, presided over by Bob Gaydos, several attendees joked that the Country of Origin project was a "keep Bob out of jail project."

68. In early March 2008, Plaintiff-Relator Cox was in a meeting with Bob Gaydos, Senior Vice President of Global Orthopedic Operations. In attendance in this meeting were Win Ellard, Neil McGee, and Paul Cirbus. Smith & Nephew's violations of several federal regulations were discussed in this meeting. Neil McGee suggested that a way around this problem was to have boxes of Smith & Nephew products marked "Proudly Packaged in the USA." Another idea considered was to have products sent to Defendant's facilities in Germany

for packaging, giving the illusion that end products purchased from non-designated countries like China had in fact been made, or at least “significantly transformed,” in Germany. During this meeting, it was acknowledged that products manufactured in Malaysia were being shipped to the United States military, along with other customers, in violation of the Federal Trade Agreement Act.

69. When Plaintiff-Relator Cox refused to aid Smith & Nephew in its illegal practices, he was berated and cursed by CIO Chiovani. In addition, Jon Schaubert threatened Plaintiff-Relator Cox, saying that he would give Mr. Cox a very poor grade on his performance review.

70. Mr. Cox reported Smith & Nephew’s fraudulent practices and retaliatory actions to Smith & Nephew’s whistleblower hotline, maintained by Defendant and administered by the Corporate Governance Committee of Smith & Nephew.

71. In September 2008, Smith & Nephew terminated Plaintiff-Relator Cox for refusing to participate in Defendant’s illegal practices and for attempting to end those practices by bringing them to the attention of his supervisors.

72. Plaintiff-Relator Cox has firsthand knowledge of information in Smith & Nephew’s possession and exclusive control containing specific evidence of the false claims and statements described in the preceding and following paragraphs. Specifically, the Material Document Number that follows every product purchased and sold by Smith & Nephew can be used to track products from their origin in Malaysia or other non-designated countries through their warehousing in Defendant’s Memphis, Tennessee facilities and their sale and shipment to the United States Government in violation of the Trade Agreements Act. This confidential information, of which Plaintiff-Relator has firsthand knowledge, will confirm with specificity the

myriad occasions on which Smith & Nephew's false certifications of TAA compliance led to violations of the False Claims Act by inducing the United States Government to pay Defendant for products that did not originate in the United States or a designated country.

73. Additional evidence already in Plaintiff-Relator's possession demonstrates that the magnitude of Smith & Nephew's fraud against the United States Government, as described above, has significantly increased in recent years as a direct and intentional result of Defendant's policies and practices.

74. As early as 2006, Smith & Nephew engaged in a concerted attempt to minimize costs and maximize profit by increasing the number of products purchased from Malaysia and China, both non-designated countries under the TAA.

75. For example, Defendant's 2006 Trauma Upstream Manufacturing Objectives demonstrate the primary importance Smith & Nephew placed on the outsourcing of products to low cost countries including Malaysia and China. *See* Exhibit 8, attached.

76. Smith & Nephew internal documents show that the Company spent over \$6,200,000 on implants supplied by Malaysia in 2006, accounting for more than 26% of Defendant's total spending on implants for that year, and making Malaysia by far Smith & Nephew's largest supplier of implants for 2006. *See* Exhibit 9, attached.

77. By February 2008, as documented in a Straits Costed Supply Plan dated February 19, 2008, Smith & Nephew estimated a total expenditure for 2008 of over \$14,800,000 on purchases from Straits. *See* Exhibit 10, attached.

78. Even as Smith & Nephew worked to increase its spending on Malaysian end products, its sales to the United States Government steadily increased. Between 2000 and 2010, doing business through a variety of parent companies, Smith & Nephew totaled approximately

\$58,300,521 in sales to the United States Government. *See* Exhibit 7.

COUNT I

(False Claims Act, 31 U.S.C. §3729(a)(1)(A), formerly (a)(1))

79. Plaintiff-Relator Cox re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

80. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729-32.

81. By virtue of the acts described above, Defendant Smith & Nephew knowingly submitted, caused to be submitted and continues to submit and to cause to be submitted false or fraudulent claims for payment and reimbursement by the United States Government by knowingly or recklessly making false statements about the country of origin of products offered for sale to the United States Government that did not originate in the United States or a designated country as defined by the Trade Agreements Act.

82. The United States, unaware of the falsity of the statements and/or claims made by the Defendant and in reliance on the accuracy thereof, paid for the aforementioned false claims because the Defendant intentionally or with gross disregard for the truth sold products to the Government that did not originate in the United States or a designated country, despite falsely certifying Defendant's compliance with the provisions of the Trade Agreements Act.

83. As set forth in the preceding paragraphs, Defendant violated 31 U.S.C. § 3729 and has thereby damaged and continues to damage the United States Government by its actions in an amount to be determined at trial.

COUNT II

(False Claims Act, 31 U.S.C. §3729(a)(1)(B), formerly (a)(2))

84. Plaintiff-Relator Cox re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

85. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729-32.

86. By virtue of the acts described above, Defendant Smith & Nephew knowingly made, used or caused to be made or used, and continues to make or use or cause to be made or used, false statements to obtain Federal Government payment for false or fraudulent claims because the Defendant falsely certified that all products it sold and offered for sale to the United States Government originated in the United States or designated countries as defined by the Trade Agreements Act, or Defendant certified that it truthfully and honestly provided accurate information to the United States Government regarding the country of origin of products that it was offering for sale to the Government, when in fact the Defendant knowingly provided false and misleading information. These were material misstatements that violated the Trade Agreements Act and/or frustrated the efforts of the United States Government to achieve its goals and policies under the Trade Agreements Act.

87. The United States was unaware of the falsity of the statements made by the Defendant and relied on the accuracy thereof because the Defendant intentionally or with gross disregard for the truth misrepresented to the Government the material issue of Defendant's conformity with the requirements of the Trade Agreements Act.

88. As set forth in the preceding paragraphs, Defendant violated 31 U.S.C. §3729 and has thereby damaged and continues to damage the United States Government by its actions in an

amount to be determined at trial.

COUNT III

(False Claims Act, 31 U.S.C. §3729(a)(1)(C), formerly (a)(3))

89. Plaintiff-Relator Cox re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

90. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729-32.

91. By virtue of the acts described above, Defendant Smith & Nephew defrauded the United States by making false and misleading statements as to its TAA compliance and/or making false claims based on those statements.

92. The United States, unaware of the falsity of the statements and/or claims made by the Defendant and in reliance on the accuracy thereof, paid for the aforementioned false claims because the Defendant intentionally or with gross disregard for the truth sold products to the Government that did not originate in the United States or a designated country, despite falsely certifying Defendant's compliance with the provisions of the Trade Agreements Act.

93. By virtue of the acts described above, Defendant defrauded the United States.

94. As set forth in the preceding paragraphs, Defendant violated 31 U.S.C. § 3729 and has thereby damaged and continues to damage the United States Government by its actions in an amount to be determined at trial.

COUNT IV

(Violation of 31 U.S.C. §3730(h), Wrongful Discharge)

95. Plaintiff-Relator Cox re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

96. Mr. Cox engaged in protected activity by repeatedly advising his supervisors that he believed that Smith & Nephew had violated the law—specifically the Trade Agreements Act’s provisions relating to country of origin of products sold to the United States Government—when Smith & Nephew offered for sale and sold products from non-designated countries to the United States Government.

97. Mr. Cox communicated his concerns about Defendant’s violations of the False Claims Act to several senior-level officials at Smith & Nephew. Mr. Cox also reported his concerns to the Smith & Nephew whistleblower hotline.

98. Soon after taking these actions, Plaintiff-Relator Cox was terminated.

99. The timing of Mr. Cox’s discharge demonstrates that his discharge was motivated, in whole or in part, by illegal animus prohibited by 31 U.S.C. Section 3730(h).

100. As a result of this discharge, Mr. Cox has sustained loss of wages, emotional distress, and embarrassment.

PRAYER

WHEREFORE, Plaintiff-Relator prays for judgment against Defendant as follows:

1. That Defendant cease and desist from violating the Trade Agreements Act;
2. That Defendant cease and desist from violating 31 U.S.C. §§ 3729 *et seq.*;
3. That this Court enter judgment against the Defendant in an amount equal to three times the amount of damages the United States Government has sustained because of Defendant’s actions, plus a civil penalty of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. §§ 3729 *et seq.*;
4. That Plaintiff-Relator be awarded the maximum amount pursuant to § 3730(d) of the False Claims Act;

5. That Plaintiff-Relator be awarded the maximum amount pursuant to § 3730(h) of the False Claims Act;

6. That Plaintiff-Relator be awarded all costs and expenses of this action, including attorneys' fees; and

7. That Plaintiff-Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff-Relator Cox hereby demands a trial by jury.

Respectfully submitted this 12th day of February, 2010

/s/

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